REMARKS

Claims 1 to 5 and 11 to 13, as amended, are pending. Applicants have canceled claims 6 to 10 in response to a restriction requirement and without prejudice to pursuing the subject matter of these claims in a continuing application. Applicants have amended claims 1 to 5 and added new claims 11 to 13. Attached hereto is a marked-up version of the changes made to the claims by the current amendment, which is captioned "**Version with markings to show changes made.**" The amendments find full support in the original specification and claims. In particular, the recitation of "spherically-shaped" ceramics finds support in the specification at, for example, page 4, lines 31 to 34. No new matter is presented. In view of the above amendments and remarks that follow, Applicants respectfully request reconsideration and a timely indication of allowance.

The Examiner rejected claims 1 to 5 under 35 U.S.C. § 103(a) as allegedly unpatenable over Unist (U.S. Patent No. 4,596,574) in view of Gombotz et al. (U.S. Patent No. 5,019,400). Applicants respectfully traverse this rejection.

Independent claim 1, as amended, recites a process for producing spherically-shaped ceramics comprising dropping a starting material for ceramics into a low temperature medium, followed by freeze drying and then sintering the same. As a result of this process, the ceramics have a spherical shape very close to a real sphere, as shown in Figs. 6(a), 7(a) and 8(a) of the present application, with a particle having a size of, for example, about 0.01 mm to a larger size of, for example, about 10 mm, which can be adjusted by the mode of contact according to the present invention. Namely, the intended size can be easily controlled by the simple steps of:

(a) dropping a starting material for ceramics into a low temperature medium;

(b) freeze-drying the resultant starting material for ceramics after dropping; and

(c) sintering the freeze-dried starting material for ceramics.

Thus, according to the present invention, the spherical size can be freely controlled by the combination of simple steps to form the spherical shape very close to a real sphere. As a result, the desired spherical-shape ceramics having the freely controlled size can be advantageously obtained at a mass production rate. The presently claimed process is neither taught nor suggested by the cited references.

Unist discloses a composition comprising a physiologically acceptable, biodegradable porous ceramic containing bone morphogenic protein (BMP) obtained by contacting a physiologically acceptable, biodegradable porous ceramic with a liquid containing substantially pure BMP and removing

the liquid therefrom so that an effective amount of BMP is entrapped in the porous ceramic. However, Unist neither teaches nor suggests the production of spherically-shaped ceramics according to the present invention. Moreover, Unist does not teach or suggest the porous sustained drug release product recited in dependent claim 3 or the method for producing the porous sustained drug release product recited in claim 12.

Gombotz discloses the preparation of polymeric microspheres for controlled release of substances by atomizing the droplets of polymer solution into a liquefied gas, followed by thawing (i.e., freeze-drying) the polymer solvent in the frozen droplets of polymer solution. However, Gombotz does not make up for the deficiencies of Unist. Namely, Gombotz does not teach or suggest the production of spherically-shaped ceramics having a controlled size using a sintering step, according to the present invention. According to the present invention, the precursor ceramic particles are subjected to an extremely severe sintering step. One skilled in the art would not expect that the spherical ceramic precursor could maintain its spherical shape and provide the porous spherically-shaped ceramic suitable for use as a bone filler, DDC carrier, medical or dental bone filler, bone cement, bioceramic material or resorbable carrier.

Accordingly, even the combination of Gombotz and Unist does not render obvious the claimed invention. Applicants therefore respectfully request that the rejection under section 103 be withdrawn.

For all these reasons, Applicants respectfully submit that pending claims 1 to 5 and 11 to 13, as amended, are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicants invite the Examiner to contact the undersigned at the number below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please amend claims 1 to 5 as follows:

1. (Amended) A process for producing spherically-shaped ceramics comprising dropping a starting material for ceramics into a low temperature medium, followed by freeze drying and then sintering the same.

2. (Amended) A process for producing spherically-shaped ceramics as claimed in claim 1, wherein the [~~ceramics~~] starting material is calcium phosphate, tricalcium phosphate, calcium dihydrogenphosphate, tetracalcium phosphate, octacalcium phosphate, or a mixture of these calcium phosphates.

3. (Amended) A sustained drug release product obtained by forming the spherically-shaped ceramics obtained according to claim 1 or 2 into a porous product, followed by impregnating the pores with a drug.

4. (Amended) A sustained drug release product as claimed in claim 3, wherein, after the drug is impregnated into the porous ceramics, the impregnated parts are plugged by said ceramics, whereby the sustained release time of the drug is controlled.

5. (Amended) A process for producing spherically-shaped ceramics[~~, wherein a ceramics solution is brought into contact with a low temperature medium~~] comprising:

bringing a starting material for ceramics into contact with a low temperature medium, followed by freeze drying and;

thereafter sintering the resultant freeze dried product.